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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/808,629 | 02/28/1997 | JAYANTA ROY-CHOWDHURY | ENZ-55 | 6556 |

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[REDACTED] EXAMINER

SCHWADRON, RONALD B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1644 | |

DATE MAILED: 01/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--------------------------------------|---|---|
| Application No. 08/808,629 | Applicant(s) Roy-Chowdhury et al. |  |
| Examiner Ron Schwadron | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 121-125 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 121-125 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

1. Applicant's election of Group I, claims 121-148 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).
2. Claims 149-155 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 10.
3. Claims 121-125 are under consideration. Claims 126-155 were canceled in page 2 of Paper No. 10.
4. Regarding the term "selective immune down regulation"(SIDR), said phrase is interpreted as per the definition of said term on paragraph one, page 7 of the instant application.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 121-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Selawry (US Patent 5,849,285).

Selawry teaches a method wherein systemic tolerance is induced to transplant antigens in a recipient, followed by administration of a graft containing the tolerized antigens (see column 8, last paragraph continued on column 9 and column 9, first complete paragraph). Selawry teach that the transplanted graft is bone marrow (see column 8, last paragraph continued on column 9). The method of Selawry induces systemic tolerance and it is an inherent property of said method that the tolerance is antigen specific (eg. said method induces SIDR). Selawry teaches that the method can be combined with treatment with other immune modulating agents (see column 9, penultimate paragraph).

7. Claims 121,122 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearson et al.

Pearson et al. teaches a method wherein systemic tolerance is induced to transplant antigens (DST) in a recipient, followed by administration of a graft containing the tolerized antigens (see page 565). The method of Pearson et al. induces tolerance to a transplanted graft, while the recipient can still reject a graft from a third party donor (eg. a donor containing MHC antigens to which tolerance has not been induced, see page 565, second column section *Specificity of the tolerant State*).

8. Claim 125 is rejected under 35 U.S.C. 102(b) as being anticipated by McMenamin et al.

McMenamin et al. teach induction of antigen specific tolerance to OVA in a recipient (see Figure 1 and page 1869, second column and third column). McMenamin et al. teach that immune cells from said tolerized recipient can be transferred to a second animal and induce tolerance to OVA in said recipient of the tolerized immune cells (see Figure 1).

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the

Serial No. 08/808629

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Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644

June 12, 2001